JAN 16 2003

GE Medical Systems

P.O. Box 414, W-400
Milwaukee, WI 53201
USA

K024200

This 510(k) summary of Safety and Effectiveness informartion is submitted in accordance with the requirements of 21 CFR 807.87(h).

Submitter: GE Medical Systems
PO Box 414
Milwaukee. WI 53201

Contact Person: Larry A. Kroger
Senior Regulatory Programs Manager
Tel: 262-544-3894; Fax: 262-548-4768

Date: 18 December 2002

Device Name: Innova 2000 and Innova 2000S (Mobile version)

Manufacturer: GE Medical Systems Europe
283 rue de la Minière
78530 Buc Cedex. France

Distributed by: GE Medical Systems
PO Box 414
Milwaukee. WI 53201

Marketed Device: Innova 2000 and Innova 2000S cleared under K022322.

Device Description: The Innova 2000 and 2000S (Mobile version) - hereafter referred to as Mobile Innova 2000 and Innova 2000S - are composed of the the same components as the predicate device.
The principle system components include a C-arm, image acquisition, processing and archiving capabilities.

Materials: Materials and construction are equivalent to

the predicate device and are compliant with UL 2601-1, IEC 60601-1 and associated collateral standards and applicable sections of 21 CFR Subchapter J.

Indications for use: The Digital Fluoroscopic Imaging systems are indicated for use in generating fluoroscopic images of the human anatomy for diagnostic and interventional cardiac angiography procedures. These systems can be operated in a mobile or fixed site environment.

Comparison with Predicate Device: The Mobile Innova 2000 and Innova 2000S systems are a modification of, and of comparable type and substantially equivalent to the currently marketed Innova 2000 and Innova 2000S systems cleared under K022322. They have the same technological characteristics, have comparable key safety and effectiveness features, use the same basic design, construction and materials and have the same intended use as the predicate devices.

Summary of Studies: The devices have been evaluated for electrical, mechanical and radiation safety and conform to applicable medical device safety and performance standards.

Conclusions: GE Medical Systems considers that the Mobile Innova 2000 and Innova 2000S systems are substantially equivalent to the currently cleared Innova 2000 and Innova 2000S systems. Their intended use and fundamental scientific technology are the same as the predicate devices. The design and development process of the manufacturer conforms with 21 CFR 820 and ISO 9001/EN 46001 quality systems. The devices also conform to applicable medical device safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 6 2003

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
P.O. Box 414, W-400
MILWAUKEE WI 53201

Re: K024200
Trade/Device Name: Innova 2000 and 2000S (Mobile version)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified Fluoroscopic x-ray system
Regulatory Class: II
Product Code: 90 MQB
Dated: December 18, 2002
Received: December 20, 2002

Dear Dr. Kroger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K024200

Device Name: **Innova 2000 and Innova 2000 S (Mobile version)**

Indications for Use

The **Digital Fluoroscopic Imaging Systems** are indicated for use in diagnostic and interventional cardiac angiography and optionally, rotational cardiac angiography procedures of human anatomy. It is intended to replace image intensifier fluoroscopic systems in all diagnostic or interventional cardiac angiography procedures. They can be operated in a mobile as well as a fixed site environment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024200